AUG 2 2 2013

5. 510(K) SUMMARY

Submitter's Name:	Flower Orthopedics Corporation
Submitter's Address:	7715 Crittenden Street, #413 Philadelphia, PA 19118
Submitter's Telephone:	267-437-3063
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Authorized Contact Name:	Janice M. Hogan
Contact's Telephone:	267-675-4611
Contact's Email:	janice.hogan@hoganlovells.com
Date Summary was Prepared:	July 26, 2013
Trade or Proprietary Name:	Flower Small and Medium Implant Set
Common or Usual Name:	Bone plating system
Classification:	Class II per 21 CFR §888.3030
Product Codes:	HRS, HWC
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	Flower Small and Medium Implant Set (K123562) Synthes USA's 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications (K082807) Stryker's VariAx Distal Radius Locked Plating System Line Extension for Addition of Aiming Blocks (K112455) KLS-Martin Hand Plating System (K040598)

CHANGE FROM PREDICATE:

The purpose of this submission is to make modifications (line extensions) to the components of the Flower Small and Medium Implant Set cleared in K123562. The standard construct is modified by adding sizes not included in the previous submission.

TECHNOLOGICAL CHARACTERISTICS:

The Flower Small and Medium Implants set consists of the following components and accessories: pure titanium small straight plates, small and medium reconstruction plates, medium osteosynthesis plates, proximal humerus plates, distal radius plates, L-shaped plates, T-plates, angular T-shaped plates, H-shaped plates, mediocarpal plate; and titanium alloy screws. The device is also provided with general purpose instruments.

INDICATIONS FOR USE

The Flower Small and Medium Implants set is intended for use for internal fixation of fractures and reconstruction of bones, including the scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, hand and foot in adults and for long bone in adolescents (12-21) in whom the growth plates have fused. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and mal-unions.

This system can be used for palmar, ventral, dorsal or orthogonal application.

PERFORMANCE DATA

In support of this 510(k) Premarket Notification, Flower Orthopedics has conducted engineering analysis to demonstrate that the modifications to the Flower Small and Medium Implants set provides adequate and substantially equivalent mechanical strength for its intended use.

CONCLUSION

The Flower Small and Medium Implants system is very similar to previously cleared Flower Small and Medium Implant Set. The Flower Small and Medium Implants system has the same intended uses and similar indications, technological characteristics, and principles of operation as the previously cleared devices. The minor technological differences between the subject Flower Small and Medium Implants and its previously cleared devices raise no new types of safety or effectiveness questions. The overall technology characteristics lead to the conclusion that Flower Small and Medium Implant Set is substantially equivalent to the previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Flower Orthopedics Corporation
% Ms. Janice M. Hogan
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K131657
Trade/Device Name: Flower Small and Medium Implant Set
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: July 26, 2013
Received: July 26, 2013

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Device Name: Flower Small and Medium Implant Set

The Flower Small and Medium Implants set is intended for use for internal fixation of fractures and reconstruction of bones, including the scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, hand and foot in adults and for long bone in adolescents (12-21) in whom the growth plates have fused. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and mal-unions.

This system can be used for palmar, ventral, dorsal or orthogonal application.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices